

**Notice of Allowability****Application No.**

09/923,304

**Applicant(s)**

KATZ ET AL.

**Examiner**

Jeanine A Goldberg

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/16/04; 4/22/04.
2. ☒ The allowed claim(s) is/are 1-3 and 11-28.
3. ☒ The drawings filed on 06 August 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance.

The claims have been amended to be drawn to a method for identifying risk for development of non-small cell lung cancer by analyzing DNA for loss of herterozygosity (LOH) in RPL14 on chromosome 3p and LOH on 10q22.

The art clearly teaches an association between LOH and non-small cell lung cancer and RPL14. Shriver et al. (Mutation Research Genomics, Vol. 406, No. 1, pages 9-23, November 1998) teaches chromosome 3p is consistently deleted in lung cancer, oral squamous cell carcinoma and renal cell carcinoma (abstract). Shriver teaches isolating a gene located at 3p21.3, namely the ribosomal protein L14 gene (RPL14)(abstract). Shriver teaches that "genotype analysis of RPL14 shows that this locus is 68% heterozygous in the normal population, compared with 25% in non-small cell lung cancer (NSCLC) cell lines ( $p = 0.008$ )" (abstract).

The claims further require analyzing 10q22.

The art teaches 10q22-q26 is associated with small cell lung cancer (SCLC) (see Petersen, Oncogene, Vol. 17, pages 449-454, 1998- applicant's reference C68). As provided in the previous rejections, there is no clear association between NSCLC and SCLC. The art does not appear to teach an association of LOH on 10q22 and NSCLC, as the claims are limited to.

The instant specification, Figure 1 and 2 illustrate the association of 3p and 10q and their associations with benign, no relapse and relapse in non-small cell carcinoma.

Therefore, screening for the combination of RPL14 and 10q22 as an indicator of a subject at risk for NSCLC would have been non-obvious in view of the art.

2. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Jeanine Goldberg**  
**Patent Examiner**  
May 5, 2004



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